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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,828	12/09/2003	Ian D. Faulkner	PZ9918 CON	4379
7590 03/15/2006 Amerhsam Health, Inc. 101 Carnegie Center Princeton, NJ 08540			EXAMINER GILBERT, SAMUEL G	
			ART UNIT 3735	PAPER NUMBER

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/731,828	FAULKNER ET AL.	
	Examiner	Art Unit	
	Samuel G. Gilbert	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/23/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-10, 12-15, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-10, 12-15, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-10, 12-15, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langton et al(5,460,592) in view of Bolea(5,863,790).

Langton teaches a method of making and sterilizing a seed train. The applicant's attention is invited to column 2 lines 60-64, showing the method of heating and subsequently cooling to make the seed train semi-rigid. Column 3 lines 10-13 that teaches the device can be stiffened and sterilized at the same time. Column 6 lines 1-3 show a temperature range of 150-185 C for 1 hour to stiffen the material. The examiner is taking element -13- as a closed container. Sleeve -28- is gas impermeable. I-125 is set forth in column 5, lines 14-21. It is inherent that the seeds are free of moisture. Regarding claim 12 – the heat is dry heat. The applicant's attention is invited to column 6, line 1. However Langton et al does not teach a time of at least two hours for sterilization. It is old and well known in the medical art that when using dry heat for sterilization the typical time period is at least two hours as shown by Bolea column 1 lines 39-42. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to use a time period of at least two hours for dry heat

sterilization for the device of Langton et al as set forth in Bolea to ensure the device is properly sterilized.

Claim 10 – It is the examiner's position that the seeds of Langton et al are inherently free of moisture but if they would include at the beginning of the dry heat sterilization process the seed would be free of moisture at the end of the dry heat sterilization process.

Claim 14 – the applicant's attention is invited to the embodiment of figure 23.

Claim 18 - it is the examiner's position that the elements are isotropic, unless specifically designed to provide a dose distribution, which is not isotropic, the radiation distribution of most seeds known in the medical arts are isotropic. The applicant has provided no evidence that the seeds of Langton et al are out of the ordinary and therefore are considered to be isotropic.

Claims 7 and 15 - the devices after sterilization are shipped the end user. The end user would need to know what specific radiation train is contained in the sterile package to decide which seed train to use. Labels are well known in the medical arts to provide end users with the information they need. The examiner is taking official notice that end user package labels are well known in the medical arts and would have been obvious to use with the container of Langton et al. to provide the end user with the required information.

Claim 8 - when using an autoclave it is known to sterilize more than one instrument at the same time. It would have been obvious to one of ordinary skill in the

art at the time the invention was made to sterilize more than one device at a time as a duplication of elements which is within the skill of one of ordinary skill in the art.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kan 6,106,455 in view of the combination of Langton et al (5,460,592) and Bolea(5,863,790) as applied to claim 1 above. Kan teaches sterilizing loose seeds with steam. Langton and Bolea teach using dry heat in the range claimed for the time claimed by the applicant. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use dry heat sterilization with the device of Kan as a substitution of functionally equivalent elements as taught by Langton et al and Bolea.

Response to Arguments

Applicant's arguments filed 12/23/2005 have been fully considered but they are not persuasive. The rejections regarding moisture and isotropic have been addressed above and are not persuasive.

Applicant's arguments with respect to claims 1+ regarding the at least two hour time period have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Samuel G. Gilbert
Primary Examiner
Art Unit 3735

sgg